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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Bendele et al.

Serial No.: 09/907,263

Group Art Unit No.: 1646

Filed: July 17, 2001

Examiner: E. O'Hara

For: COMBINATION THERAPY USING A TNF BINDING
PROTEIN FOR TREATING TNF-MEDIATED
DISEASES

Docket No.: A-430F

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

As a means of complying with the duty of disclosure, applicants submit a "List of References Cited by Applicant" on a modified PTO-1449 form. The relevance of each listed reference is discussed in the following paragraphs.

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, or before the mailing of a first Office action after the filing of a request for continued examination under section 1.114, whichever event occurs last. 37 CFR 1.97(b).

Applicants request consideration of this information and passage of the application to issue.

The Commissioner is hereby authorized to charge any filing fees which may be required or credit any overpayment to Deposit Account No. 01-0519 in the name of Amgen Inc.

Respectfully submitted,

Timothy J. Gaul
Attorney for Applicants
Registration No.: 33,111
Phone: (805) 447-2688
Date: August 30, 2002

Please send all future correspondence to:
US Patent Operations/ TJG
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One Amgen Center Drive
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EXPRESS MAIL CERTIFICATE

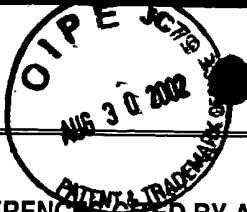
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Modified Form PTO-1449 LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)	Atty. Docket No. A-430F	Serial No. 09/907,263
	Applicant Bendele et al.	
	Filing Date July 17, 2001	Group

U.S. PATENT DOCUMENTS

EXAMINER'S INITIALS		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
	A003	4,670,563	6/02/87	Jansen et al. (English equivalent of EP 0 169 112)			
	A004	5,075,222	12/24/91	Hannum et al.			
	A005	5,093,475	3/3/92	Merrill			
	A006	5,344,915	9/06/94	LeMaire et al.			
	A007	5,466,823	11/14/95	Talley et al.			
	A008	5,563,165	10/8/96	Talley et al.			
✓	A009	5,605,690	02/25/97	Smith et al.			
	A010	5,691,374	11/25/97	Black et al.			
	A011	5,731,343	03/24/98	Feng et al.			
	A012	5,760,068	6/2/98	Talley et al.			
	A013	5,795,967	08/18/98	Aggarwal et al.			
	A014	5,958,409	9/28/99	Turk et al.			
	A015	5,972,986	10/26/99	Seibert et al.			
	A016	6,063,811	5/16/00	Hancock et al.			
	A017	6,096,728	8/01/00	Collins et al.			

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Applicant	Bendele et al.		
Filing Date	July 17, 2001	Group	

FOREIGN PATENT DOCUMENTS

EXAMINER'S INITIALS	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	TRANSLATION YES NO
	B003	WO 01/00229 A1	01/04/01	PCT		
	B004	WO 00/48583	08/24/00	PCT		
	B005	WO 98/16227	04/23/98	PCT		
	B006	WO 98/05357	02/12/98	PCT		
	B007	WO 96/26271	8/29/96	PCT		
	B008	WO 96/20729	07/11/96	PCT		
	B009	WO 96/19459 A1	06/27/96	PCT		
	B010	WO 94/06476	03/31/94	PCT		
	B011	WO 92/07585	05/14/92	PCT		
	B012	WO 92/01474 A1	2/06/92	PCT		
	B013	WO 90/14363	11/29/90	PCT		
	B014	WO 89/05145 A1	06/15/89	PCT		
	B015	EP 0 927 555	07/07/99	Europe		
	B016	EP 0 386 289 A1	9/12/90	Europe		
	B017	EP 0 247 860 A2	12/02/87	Europe		
	B018	EP 0 225 579 A3	6/16/87	Europe		
	B019	EP 0 169 112 B1	1/22/86	Europe (see U.S. 4,670,563 for English)		
	B020	EP 0 154 316 B1	9/11/85	Europe		
	B021	EP 0 154 316 A2	9/11/85	Europe		

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EXAMINER'S INITIALS

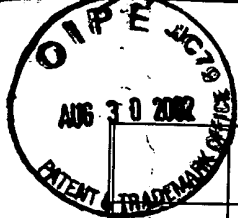
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

C004	Baker et al. (1992), "Inhibition of EAE by TNF-Receptor Fusion Proteins", <i>J. Neuroimmunology</i> , 54(1-2):151 Abstract P16.01.
C005	Bakouche et al. (1988), "Plasma Membrane-Associated Tumor Necrosis Factor, A Non-Integral Membrane Protein Possibly Bound to Its Own Receptor", <i>J. Immunol.</i> 140:1142-1147.
C006	Banner et al. (1993), "Crystal Structure of the Soluble Human 55 KD TNF Receptor-Human TNF β Complex: Implications for TNF Receptor Activation", <i>Cell</i> , 73:431-445.
C007	Barrera et al. (1993), "Circulating Soluble Tumor Necrosis Factor Receptors, Interleukin-2 Receptors, Tumor Necrosis Factor Alpha, and Interleukin-6 Levels in Rheumatoid Arthritis. Longitudinal Evaluation During Methotrexate and Azathioprine Therapy", <i>Arthritis and Rheumatism</i> 36(8):1070-1089.
C008	Barrera et al. (1996), "Effects of Antirheumatic Agents on Cytokines", <i>Seminars in Arthritis and Rheumatism</i> , 25(4):234-253.
C009	Bevilacqua et al. (1986), "Recombinant tumor necrosis factor induces procoagulant activity in cultured human vascular endothelium: Characterization and comparison with the actions of interleukin 1", <i>Proc. Natl. Acad. Sci. USA</i> , 83:4533-4537.
C010	Bologna et al. (1996), "Association Destraitements de Fond Dans La Polyarthrite Rhumatoide," <i>Presse Medicale</i> 25(19):876-878.
C011	Borigini et al. (1995), "Combination Therapy," <i>Bailliere's Clin. Rheuma.</i> 9(4):689-710.
C012	Brakebusch et al. (1993), "Diverse Functions of the Tumor Necrosis Factor Receptors: Structure-Activity Considerations", <i>Tumor Necrosis Factor: Molecular and Cellular Biology and Clinical Relevance</i> , Fiers W. Buurman WA (eds.) Basel. Karger, pgs. 40-51.
C013	Braun et al. (2000), "Anti-TNF-alpha: A New Dimension in the Pharmacotherapy of the Spondyloarthropaties?," <i>Annals of the Rheumatic Diseases</i> 59(6):404-406.
C014	Butler et al. (1994), "TNF Receptor Fusion Proteins Are Effective Inhibitors of TNF-Mediated Cytotoxicity On Human KYM-1D4 Rhabdomyosarcoma Cells," <i>Cytokine</i> , 6(6):616-623.
C015	Capaldi et al. (1977), "Changes in Order of Migration of Polypeptides in Complex III and Cytochrome c Oxidase under Different Conditions of SDS Polyacrylamide Gel Electrophoresis," <i>Biochem. & Biophys. Res Comm.</i> 74(2):425-433.
C016	Carlino et al. (1987), "Use of a Sensitive Receptor Binding Assay to Discriminate Between Full-Length and Truncated Human Recombinant TNF Proteins", <i>J. Biol. Chem.</i> 262(3):958-961.
C017	Carrieri et al. (1992), "Cytokines in the Pathogenesis of Multiple Sclerosis", <i>Acta Neurologica</i> , 14(4-6):333-341.
C018	Chih-Hsueh Chen P. et al. (1995), "Mapping the Domain(s) Critical for the Binding of Human Tumor Necrosis Factor-Alpha to its Two Receptors", <i>The Journal of Biological Chemistry</i> , 270(6):2874-2878.

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Date Considered:

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

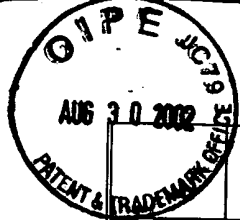


C019	Cronstein et al. (1994), "Adenosine Mediates the Antiinflammatory Effects of the Adenosine Kinase Inhibitor GP-1-515 in The Murine Air Pouch Model of Inflammation", <i>Arthritis & Rheumatism</i> , 37(9):201.
C020	Delgado et al. (1992), "The Uses and Properties of PEG-Linked Proteins," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> , 9(3,4):249-304.
C021	Dembic et al. (1990), "Two Human TNF Receptors Have Similar Extracellular, But Distinct Intracellular, Domain Sequences," <i>Cytokine</i> , 2(4):231-237.
C022	Dyson et al. (1990), "Influence of SK & F 95587 and BN 50730 on Bronchoconstrictor Responses in the Cat", <i>The Journal of Pharmacology and Experimental Therapeutics</i> , 255(3):1320-1327.
C023	Emmendorffer et al., "Treatment of Autoimmune MRL-LPR Mice with a Recombinant Human Tumor Necrosis Factor Receptor Construct", 1996 Meeting Abstracts
C024	Espevik et al. (1990), "Characterization of Binding and Biological Effects of Monoclonal Antibodies Against a Human Tumor Necrosis Factor Receptor", <i>Journal Exp. Med.</i> , 171:415-426.
C025	Evans, Ronald M. (1998), "The Steroid and Thyroid Hormone Receptor Superfamily," <i>Science</i> 240:889-895.
C026	Fu Z. -Q. (1995), "Model complexes of tumor necrosis factor-alpha with receptors R1 and R2", <i>Protein Engineering</i> , 8(12):1233-1241.
C027	Glass et al. (1979), "4-Phenoxy-3,5-Dinitrobenzoylpolyethyleneglycol: Reversible Attachment of Cysteine-Containing Polypeptides to Polymers in Aqueous Solutions", <i>Biopolymers</i> , 18:383-392.
C028	Hallenbeck & Frerichs (1993), "Stroke Therapy: It May Be Time For An Intergrated Approach", <i>Arch. Neurol.</i> 50:768-770.
C029	Hass et al. (1995), "Characterization of Specific High Affinity Receptors for Human Tumor Necrosis Factor on Mouse Fibroblasts," <i>J. Biol. Chem.</i> 260(22):12214-12218.
C030	Heller et al. (1990), "Amplified Expression of Tumor Necrosis Factor Receptor in Cells Transfected with Epstein-Barr Virus Shuttle Vector cDNA Libraries," <i>J. Biol. Chem.</i> , 265(10):5708-5717.
C031	Hilliquin et al. (1995), "Treatment of Rheumatoid Arthritis with Platelet Activating Factor Antagonist BN 50730", <i>The Journal of Rheumatology</i> , 22(9):1651-1654.
C032	Hilliquin et al. (1995), "Treatment of Carrageenan Induced Arthritis By The Platelet Activating Factor Antagonist BN 50730", <i>Annals of the Rheumatic Diseases</i> , 54:140-143.
C033	Hoes et al. (1995), "Optimization of Macromolecular Prodrugs of the Antitumor Antibiotic Adriamycin", <i>Journal of Controlled Release</i> , 2:205-213.
C034	Horner et al. (1983), "Aryl-vinylsulfone-reagentien Zum Schutz Und Nachweis Von Thiofunktionen," <i>Phosphorus and Sulfur</i> 15:1-8.
C035	Israel et al. (1986), "Binding of Human TNF- α to High-Affinity Cell Surface Receptors: Effect of IFN," <i>Immunol. Lett.</i> 12:217-224.
C036	Jenkins et al. (1992), "Tumour Necrosis Factor Causes an Increase in Axonal Transport of Protein and Demyelination in the Mouse Optic Nerve", <i>Journal of Neurological Sciences</i> , 108:99-104.
C037	Kavanaugh et al. (1996), "Anti-TNF-alpha Monoclonal Antibody (MAB) Treatment of Rheumatoid Arthritis (RA) Patients with Active Disease on Methotrexate (MTX); Results of a Double-Blind, Placebo Controlled Multicenter Trial," <i>Arthritis & Rheumatism</i> 39(9):S123.

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Date Considered:

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Sheet 5 of 6
TECH CENTER 1606/2900

C038	Kogan, Timothy (1992), "The Synthesis of Substituted Methoxy-Poly(EthyleneGlycol) Derivatives Suitable for Selective Protein Modification", <i>Synthetic Communications</i> , 22(16):2417-2424.
C039	Kumar et al. (1999), "Analgesic and Anti-Inflammatory Effects of Phosphodiesterase Inhibitors," <i>Indian Journal of Experimental Biology</i> 38(1):26-30.
C040	Liblau et al. (1992), "Tumor Necrosis Factor- α and Disease Progression in Multiple Sclerosis," <i>New Engl. J. Med.</i> 326(4):272-273.
C041	Lorenz et al. (2000), "Biological Agents: A Novel Approach to the Therapy of Rheumatoid Arthritis," <i>Exp. Opin. Invest. Drugs</i> p. 1479-1490.
C042	Marangonore et al. (1990), "Design and Characterization of Hirulogs: A Novel Class of Bivalent Peptide Inhibitors of Thrombin", <i>Biochemistry</i> , 29:7095-7101.
C043	Martin et al. (1995), "Inhibition of Tumor Necrosis Factor Is Protective Against Neurologic Dysfunction After Active Immunization of Lewis Rats with Myelin Basic Protein," <i>Exp. Neurol</i> , 131:221-228.
C044	McFarland, Henry (1995), "Therapeutic Approaches to Multiple Sclerosis", <i>J. Neurochem.</i> , 64(Suppl.):S73 (Abstract C).
C045	Miller-Blair et al. (1993), "Rheumatoid arthritis: New science, new treatment", <i>Geriatrics</i> , 48(6):28-38.
C046	Monastra et al. (1993), "Phosphatidylserine, a Putative Inhibitor of Tumor Necrosis Factor, Prevents Autoimmune Demyelination", <i>Neurology</i> , 43:153-163.
C047	Moreland et al. (1997), "Etanercept Therapy in Rheumatoid Arthritis," <i>Ann Intern Med.</i> 130(6):478-486.
C048	Moreland et al. (1999), "Treatment of Rheumatoid Arthritis With A Recombinant Human Tumor Necrosis Factor Receptor (p75)-Fc Fusion Protein," <i>N. England Journal of Medicine</i> 337(3):141-147.
C049	Neda, Hiroshi (1987), "Analysis of the Tumor Necrosis Factor (TNF) Receptor of Various Tumor Cells," <i>Sapporo Medical Journal</i> , 56(2):305-317 (Abstract in English, first page).
C050	Piguet et al. (1989), "Tumor Necrosis Factor/Cachectin Plays a Key Role in Bleomycin-Induced Pneumopathy and Fibrosis," <i>J. Exp. Med.</i> 170:655-663.
C051	Portoghese et al. (1986), "Opioid Agonist and Antagonist Bivalent Ligands. The Relationship Between Spacer Length and Selectivity at Multiple Opioid Receptors", <i>J. Med. Chem.</i> , 29:1855-1861.
C052	Powell et al. (1992), "The Role of Lymphotoxin and TNF in Demyelinating Diseases of the CNS", <i>Tumor Necrosis Factors: The Molecules and Their Emerging Role in Medicine</i> , ed. by B. Beutler; Raven Press, New York, pgs. 355-369.
C053	Powell et al. (1990), "Lymphotoxin and tumor necrosis factor-alpha production by myelin basic protein-specific T cell clones correlates with encephalitogenicity", <i>International Immunology</i> , 2(6): 539-544.
C054	Richardson et al. (1995), "New Therapies for Rheumatoid Arthritis", <i>Br. J. Clin. Pract.</i> 49(3):135-139.
C055	Ruddle et al. (1990), "An Antibody to Lymphotoxin and Tumor Necrosis Factor Prevents Transfer of Experimental Allergic Encephalomyelitis," <i>J. Exp. Med.</i> 172:1193-1200.
C056	Schacht (1993), "The Current and Future Therapy Strategies of Rheumatoid Arthritis", <i>Zeitschrift fur Rheumatologie</i> , 52:365-382.
C057	Scallon, et al. (1995), "Functional Comparisons of Different Tumor Necrosis Factor Receptor/IgG Fusion Proteins," <i>Cytokine</i> , 7(8): 759-770.

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Date Considered:

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



C058	Seitz et al. (1995), "Methotrexate Action in Rheumatoid Arthritis: Stimulation of Cytokine Inhibitor and Inhibition of Chemokine Production by Peripheral Blood Mononuclear Cells," <i>British Journal of Rheumatology</i> 34(7):602-609.
C059	Seitz et al. (1996), "Interleukin 1 (IL-1) Receptor Antagonist, Soluble Tumor Necrosis Factor Receptors, IL-1 Beta, and IL-8--Markers of Remission in Rheumatoid Arthritis During Treatment With Methotrexate," <i>Journal of Rheumatology</i> 23(9):1512-1516.
C060	Selmaj et al. (1991), "Anti-Tumor Necrosis Factor Therapy Abrogates Autoimmune Demyelination", <i>Annals of Neurology by Am. Neurol. Assoc.</i> , 30(5):694-700.
C061	Selmaj et al. (1994), "Prevention of CHR-EAE with Soluble TNF Receptor P55 ", <i>J. Neuroimmunology</i> , 54(12):196, Abstract W15.05.
C062	Selmaj et al. (1995), "Prevention of Chronic Relapsing Experimental Autoimmune Encephalomyelitis by Soluble Tumor Necrosis Factor Receptor I", <i>J. Neuroimmunology</i> , 56:135-141.
C063	Selmaj et al. (1990), "Proliferation of Astrocytes In Vitro In Response to Cytokines: A Primary Role for Tumor Necrosis Factor," <i>J. Immunol.</i> 144(1):129-135.
C064	Selmaj et al. (1998), "Tumor Necrosis Factor Mediates Myelin and Oligodendrocyte Damage In Vitro," <i>Annals of Neurology</i> 23(4):339-346.
C065	Sharief et al. (1991), "Association Between Tumor Necrosis Factor-Alpha and Disease Progression in Patients With Multiple Sclerosis," <i>New England J of Med.</i> 325(7):467-472.
C066	Shimohigashi et al. (1982), "Dimeric Tetrapeptide Enkephalins Display Extraordinary Selectivity for the δ Opiate Receptor," <i>Nature</i> , 297:333-335.
C067	Simon et al. (2000), "New and Future Drug Therapies for Rheumatoid Arthritis," <i>Rheumatology</i> 39:36-42.
C068	Socher et al. (1987), "Antibodies against amino acids 1-15 of tumor necrosis factor block its binding cell-surface receptor," <i>Proc. Natl. Acad. Sci. USA</i> 84:8829-8833.
C069	Suffys et al. (1988), "Involvement of a Serine Protease in Tumour-Necrosis-Factor-Mediated Cytotoxicity," <i>Eur. J. Biochem.</i> 178:257-265.
C070	The Cytokine Factsbook, Callard (ed.), Academic Press Inc., San Diego, CA., pp. 244-246 (1994).
C071	Tracey et al. (1988), "Cachectin/Tumor Necrosis Factor Induces Cachexia, Anemia, and Inflammation," <i>J. Exp. Med.</i> 167:1211-1227.
C072	Unglaub et al. (1987), "Downregulation of Tumor Necrosis Factor (TNF) Sensitivity Via Modulation of TNF Binding Capacity by Protein Kinase C Activators," <i>J. Exp. Med.</i> 166:1788-1797.
C073	Weber et al. (1984), "Production of an Epidermal Growth Factor Receptor-Related Protein," <i>Science</i> 224:294-297.
C074	Weisman et al. (1990), "Soluble Human Complement Receptor Type I: In Vivo Inhibitor of Complement Suppressing Post-Ischemic Myocardial Inflammation and Necrosis", <i>Science</i> , 249:146-151).
C075	Zeigler, Elizabeth J. (1988), "Tumor Necrosis Factor in Humans," <i>New Engl. J. Med.</i> 318(23):1533-1535.

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Date Considered:

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.